

# Scientific Integrity and Human Research Ethics at EPA

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## **The Vulnerabilities Inherent in the *Status Quo*:**

- EPA's human research ethics program does not meet accepted standards in the bioethics community and is widely regarded as inadequate by knowledgeable individuals.
- EPA's human studies rule is seriously flawed, contains barriers to ethically desirable human research, and impedes interagency collaborations.
- EPA has a history of regulatory violations involving human research (details available).
- If public scrutiny is brought to bear because of a new adverse event, EPA's inability to demonstrate that the Agency meets accepted standards could cause further harm to EPA's post-CHEERS reputation and thereby compromise the Agency's mission.
- A current example is the allegation that the experimental building demolition carried out by EPA in Ft. Worth, TX in 2007 constituted human research without informed consent.

## **The Solution:**

- An independent, integrated scientific integrity-human research ethics program with resources appropriate to its mandate and a direct reporting line to a senior EPA official.

## **Programmatic Functions:**

- Comprehensive regulatory oversight of human research conducted or supported by EPA.
- Development of guidance and new regulations to address flaws in the current EPA human studies rule and gaps in existing guidance from the DHHS Office for Human Research Protections (which has a biomedical, not an environmental, focus).
- Integration of human research protection activities into the grant-making process.
- An intramural human research protection program that meets accreditation standards.
- Support for the OPP third-party human research oversight program, including operation of the EPA Human Studies Review Board.
- A scientific integrity program that extends to intramural *and* extramural activities.
- Outreach to Program Offices, Regions, and the regulated community in the private sector.
- Bioethics consultation for EPA scientists, public health practitioners, and policymakers.
- Scholarship in bioethics relevant to matters within the scope of EPA's interests.

## **Start-up Personnel Resources:**

- Program Director (existing)
- Administrative Assistant (existing)
- HSRB Designated Federal Officer (existing)
- Education Officer (new)
- Compliance Officer (new)
- Human Research Protection Program Administrator (new)
- Research Integrity Officer (new)